Laboratory Name _____

EPA Laboratory ID (if known) _____ **DCLS Checklist Reviewer (initials/date)** _____

QUALITY MANUAL CHECKLIST FOR NEW APPLICANTS – 1 VAC 30-46

Please indicate by section number and/or page number, where the following elements are found in the submitted Laboratory Quality Manual. ***SUBMIT DOCUMENTATION AS NOTED.***

Mandatory Quality Elements & 2003 NELAC Standards, Chapter 5, References	Laboratory Reference	Document Compliant			Comments and Corrective Actions
		Y	N	N/A	(DCLS USE ONLY)
5.4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system. The quality manual and related documentation shall state the laboratory's policies and operational procedures established in order to meet the requirements of the standard. The quality manual and related quality documentation shall contain:					
5.4.2.3 Title page, including document title, lab's name & address, telephone number of individual(s) responsible for lab, name of QA officer, identification of major organizational units covered by the manual & effective date					
5.4.2.3 (f) Identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual must have the signed and dated concurrence (with appropriate titles) of all responsible parties including the quality manager (s), technical director(s) and the agent who is in charge of all laboratory activities such as the laboratory director or laboratory manager					
5.4.2.3 (v) Table of contents and applicable lists of references, glossaries & appendices					
5.4.2.3 (a) Quality policy statement, including objectives & commitments by top management					
5.4.2.3 (b) Organization & management structure, organizational charts, relationship to parent organization					
5.4.2.3 (c) Relationship between management, technical operations, support services & quality system					
5.4.2.4 Roles & responsibilities of technical management & the quality manager, including their responsibility for ensuring compliance with NELAC standards					
5.4.2.3 (t) Procedures for establishing that personnel are adequately experienced and/or receive any needed training. **SUBMIT AN ANALYST'S COMPLETE TRAINING RECORD, INCLUDING SUPPORTIVE DEMONSTRATION OF CAPABLITY DOCUMENTATION.**					DATA REVIEW REQUIRED.
5.4.2.3 (e) Job descriptions of key staff, plus reference to job descriptions of other staff					
5.4.2.6 Procedures for establishing & maintaining data integrity, including training, documentation & monitoring. **SUBMIT A COPY OF THE DATA INTEGRITY POLICY (IF NOT IN THE QM) AS WELL AS THE SIGNATURE LOG FROM THE LAST TRAINING SESSION.**					DATA REVIEW REQUIRED.
5.4.2.3 (r) Procedures for protecting confidentiality & proprietary rights (including national security concerns)					
5.4.2.3 (d) Procedures for control & maintenance of documentation; document control system					

Laboratory Name _____

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QUALITY MANUAL CHECKLIST FOR NEW APPLICANTS – 1 VAC 30-46

Please indicate by section number and/or page number, where the following elements are found in the submitted Laboratory Quality Manual. ***SUBMIT DOCUMENTATION AS NOTED.***

5.4.2.3 (i) Procedures for reviewing new work & ascertaining appropriateness of facilities & resources prior to commencing new work					
5.4.2.3 (q) Procedures for dealing with complaints.					
5.4.2.3 (p) Management arrangements for permitting departures from documented procedures or standard specifications					
5.4.2.3 (o) Procedures followed for feedback & corrective action when testing discrepancies are detected or when departures to documented policies & procedures occur. **SUBMIT AN EXAMPLE OF DOCUMENTATION FOR CORRECTIVE ACTION TAKEN FOR A FAILED PT OR OTHER POLICY DEPARTURE WITHIN THE LAST 6 MONTHS.**					DATA REVIEW REQUIRED.
5.4.2.3 (s) Procedures for audits & data review					
5.4.2.3 (h) List of all test methods under which accredited testing is performed. **SUBMIT TWO STANDARD OPERATING PROCEDURES FOR REQUESTED METHODS.**					DATA REVIEW REQUIRED.
5.4.2.3 (g) Procedures for achieving traceability of measurements. (This requirement refers to documentation linking a measurement to the specific lot numbers of equipment, standards, reagents, and media used to achieve the measurement.) **SUBMIT SAMPLES FROM TWO DIFFERENT ANALYSES DEMONSTRATING DOCUMENTATION OF TRACEABILITY OF MEASUREMENTS TO THE SPECIFIC EQUIPMENT, STANDARDS, REAGENTS, AND MEDIA USED.**					DATA REVIEW REQUIRED.
5.4.2.3 (l) Reference to major equipment, reference standards, facilities & services used in conducting tests					
5.4.2.3 (m) Reference to procedures for calibration, verification & maintenance of equipment.					
5.4.2.3 (k) Procedures for handling submitted samples. **SUBMIT AN EXAMPLE PAGE FROM THE LABORATORY'S SAMPLE RECEIVING LOG.**					DATA REVIEW REQUIRED.
5.4.2.3 (j) Reference to calibration and/or verification test procedures used. **SUBMIT AN EXAMPLE OF THE LABORATORY'S CALIBRATION DATA AND ASSOCIATED QUALITY CONTROL FOR TWO ANALYSIS METHODS.**					DATA REVIEW REQUIRED.
5.4.2.3 (n) Reference to verification practices (e.g., proficiency testing, interlaboratory comparisons, use of reference materials & internal QC schemes)					
5.4.2.3 (u) Reference to procedures for reporting analytical results					